

CLAIMS

1. A method of diagnosing breast cancer or a predisposition to developing breast cancer in a subject, comprising determining a level of expression of a breast cancer-associated gene in a patient-derived biological sample selected from the group consisting of A5657, B9769, and C7965, wherein an increase in said sample expression level as compared to a normal control level of said gene indicates that said subject suffers from or is at risk of developing breast cancer.
2. The method of claim 1, wherein said sample expression level is at least 10% greater than said normal control level.
3. The method of claim 1, wherein said breast cancer-associated gene is selected from the group consisting of the A5657 gene, further wherein an increase in said sample expression level as compared to a normal control level indicates said subject suffers from or is at risk of developing IDC.
4. The method of claim 3, wherein said sample expression level is at least 10% greater than said normal control level.
5. The method of claim 1, wherein said method further comprises determining the level of expression of a plurality of said breast cancer-associated genes.
6. The method of claim 1, wherein gene expression level is determined by a method selected from the group consisting of:
 - (a) detecting mRNA of a breast cancer-associated gene selected from the group consisting of A5657, B9769, and C7965,
 - (b) detecting a protein encoded by a breast cancer-associated gene selected from the group consisting of A5657, B9769, and C7965, and
 - (c) detecting a biological activity of a protein encoded by a breast cancer-associated gene selected from the group consisting of A5657, B9769, and C7965.
7. The method of claim 6, wherein said detection is carried out on a DNA array.
8. The method of claim 1, wherein said patient-derived biological sample comprises a breast tissue.
9. The method of claim 8, wherein said breast tissue comprises an epithelial cell.

- 76 -

10. The method of claim 1, wherein said patient-derived biological sample comprises a breast cancer cell.

11. The method of claim 1, wherein said patient-derived biological sample comprises an epithelial cell from a breast cancer cell.

5 12. A method of screening for a compound for treating or preventing breast cancer, said method comprising the steps of:

a) contacting a test compound with a polypeptide encoded by a polynucleotide selected from the group consisting of A5657, B9769, and C7965;

b) detecting the binding activity between the polypeptide and the test compound; and

10 c) selecting the test compound that binds to the polypeptide.

13. A method of screening for a compound for treating or preventing breast cancer, said method comprising the steps of:

a) contacting a candidate compound with a cell expressing one or more marker genes, wherein the one or more marker genes is selected from the group consisting of
15 A5657, B9769, and C7965; and

b) selecting the candidate compound that reduces the expression level of said one or more marker as compared to a control.

14. The method of claim 13, wherein said cell comprises a breast cancer cell.

15. A method of screening for a compound for treating or preventing breast cancer, said
20 method comprising the steps of:

a) contacting a test compound with a polypeptide encoded by a polynucleotide selected from the group consisting of A5657, B9769, and C7965;

b) detecting the biological activity of the polypeptide of step (a); and

c) selecting the test compound that suppresses the biological activity of said
25 polypeptide as compared the biological activity of said polypeptide detected in the absence of the test compound.

16. A method of screening for compound for treating or preventing breast cancer, said method comprising the steps of:

a) contacting a candidate compound with a cell into which a vector, comprising the
30 transcriptional regulatory region of one or more marker genes selected from the

- 77 -

group consisting of A5657, B9769, and C7965 and a reporter gene that is expressed under the control of the transcriptional regulatory region, has been introduced;

- b) measuring the expression level or activity of said reporter gene; and
- c) selecting the candidate compound that reduces the expression level or activity of said reporter gene as compared to a control.

17. The method of claim 12, wherein said breast cancer is IDC, said method comprises the steps of:

- a) contacting a test compound with a polypeptide encoded by A5657 ;
- b) detecting the binding activity between the polypeptide and the test compound; and
- c) selecting the test compound that binds to the polypeptide.

18. The method of claim 13, wherein said breast cancer is IDC and said method comprises the steps of:

- a) contacting a candidate compound with a cell expressing A5657; and
- b) selecting the candidate compound that reduces the expression level of A5657 , as compared to a control.

19. The method of claim 18, wherein said cell comprises an IDC cell.

20. The method of claim 15, wherein said breast cancer is IDC and said method comprises the steps of:

- a) contacting a test compound with a polypeptide encoded by A5657;
- b) detecting the biological activity of the polypeptide of step (a); and
- c) selecting the test compound that suppresses the biological activity of said polypeptide as compared to the biological activity of said polypeptide detected in the absence of the test compound.

21. A method of claim 16, wherein said breast cancer is IDC and said method comprises the steps of:

- a) contacting a candidate compound with a cell into which a vector, comprising the transcriptional regulatory region of A5657 and a reporter gene that is expressed under the control of the transcriptional regulatory region, has been introduced;
- b) measuring the expression level or activity of said reporter gene; and
- c) selecting the candidate compound that reduces the expression level or activity of said reporter gene as compared to a control.

22. A kit comprising a detection reagent which binds to two or more nucleic acid sequences selected from the group consisting of A5657, B9769, and C7965, or polypeptides encoded thereby.

23. A method of treating or preventing breast cancer in a subject comprising administering to said subject an antisense composition, said antisense composition comprising a nucleotide sequence complementary to a coding sequence corresponding to a gene selected from the group consisting of A5657, B9769, and C7965.

24. A method of treating or preventing breast cancer in a subject comprising administering to said subject an siRNA composition, wherein said siRNA composition reduces the expression of a nucleic acid sequence selected from the group consisting of A5657, B9769, and C7965.

25. The method of claim 24, wherein said siRNA comprises the sense strand comprising a nucleotide sequence selected from the group consisting of nucleotide sequences of SEQ ID NO: 28, 29, 30, 31, 32, 33, and 34.

26. A method for treating or preventing breast cancer in a subject comprising the step of administering to said subject a pharmaceutically effective amount of an antibody or immunologically active fragment thereof that binds to a protein encoded by any one gene selected from the group consisting of A5657, B9769, and C7965.

27. A method of treating or preventing breast cancer in a subject comprising administering to said subject a vaccine comprising a polypeptide encoded by a nucleic acid selected from the group consisting of A5657, B9769, and C7965 or an immunologically active fragment of said polypeptide, or a polynucleotide encoding the polypeptide.

28. A method for inducing anti-tumor immunity, said method comprising the step of contacting with an antigen presenting cell a polypeptide, a polynucleotide encoding said polypeptide, or a vector comprising the said polynucleotide, wherein the polypeptide is encoded by a gene selected from the group consisting of A5657, B9769, and C7965, or a immunologically active fragment thereof.

29. The method for inducing anti-tumor immunity of claim 27, wherein the method further comprises the step of administering the antigen presenting cell to a subject.

30. A method for treating or preventing breast cancer in a subject, said method comprising the

step of administering a compound obtained by a method according to any one of claims 12-21.

31. The method of claim 23, wherein said breast cancer is IDC and said antisense composition comprises a nucleotide sequence complementary to a coding sequence corresponding to A5657.

32. The method of claim 24, wherein said breast cancer is IDC and said siRNA composition reduces the expression A5657.

33. The method of claim 32, wherein said siRNA comprises the sense strand comprising a nucleotide sequence of SEQ ID NO: 28 or 29.

34. The method of claim 26, wherein said breast cancer is IDC and said antibody or fragment thereof binds to a protein encoded by A5657.

35. The method of claim 27, wherein said breast cancer is IDC and said vaccine comprises a polypeptide encoded by A5657, or an immunologically active fragment of said polypeptide, or a polynucleotide encoding said polypeptide.

36. The method of claim 30, wherein said breast cancer is IDC and said compound is obtained by a method according to any one of claims 17-21.

37. A composition for treating or preventing breast cancer, said composition comprising a pharmaceutically effective amount of an antisense polynucleotide or small interfering RNA against a polynucleotide selected from the group consisting of A5657, B9769, and C7965.

38. The composition of claim 37, wherein said siRNA comprises the sense strand comprising a nucleotide sequence selected from the group consisting of nucleotide sequences of SEQ ID NO: 28, 29, 30, 31, 32, 33, and 34.

39. A composition for treating or preventing breast cancer, said composition comprising a pharmaceutically effective amount of an antibody or fragment thereof that binds to a protein encoded by a gene selected from the group consisting of A5657, B9769, and C7965.

40. A composition for treating or preventing breast cancer, said composition comprising as an active ingredient a pharmaceutically effective amount of a compound selected by a

- 80 -

method of any one of claims 12-16, and a pharmaceutically acceptable carrier.

41. The composition of claim 37, wherein said breast cancer is IDC and said polynucleotide is A5657.

42. The composition of claim 41, wherein said siRNA comprises the sense strand comprising
5 a nucleotide sequence of SEQ ID NO: 28 or 29.

43. The composition of claim 39, wherein said breast cancer is IDC and said protein is encoded by A5657 .

44. The composition of claim 40, wherein said breast cancer is IDC and said compound is selected by a method of any one of claims 17-21.